UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,505	06/05/2006	Mei Wang	1328-28	2905

23117 7590 03/08/2010

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
GITOMER, RALPH J	
ART UNIT	PAPER NUMBER
1657	
MAIL DATE	DELIVERY MODE
03/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,505	WANG ET AL.	
	Examiner	Art Unit	
	Ralph Gitomer	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *20-24 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/GB/08) Paper No(s)/Mail Date *3/3/06, 12/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election with traverse of Group I, claims 1-19, 25, in the reply filed on 12/29/09 is acknowledged. The traversal is on the ground(s) that examination of all the claims would not be a serious burden. This is not found persuasive because the inventions are distinct for the reasons given.

The requirement is still deemed proper and is therefore made FINAL.

The elected specie is biomarkers. Please inform the examiner of all related applications and their status. Upon resolution of the following issues and possible clarification of the invention, further searching and/or consideration will be required.

The point of novelty considered here is employing multivariate analysis which is interpreted to mean analyzing data from more than one variable or in this case measurement.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-24, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Huyn, Borisy, Afeyan, Khwaja, Pugh.

Huyn (2002/0095260) entitled "Methods for Efficiently Mining Broad Data Sets for Biological Markers" teaches in the abstract, determining measurements from blood samples of biomarkers for assessing response to a drug. In column 1 first paragraph, various statistical methods of interpreting data is discussed.

Borisy (2003/0096309) entitled "Screening System for Identifying Drug-Drug Interactions and Methods of Use Thereof" teaches in paragraph 20 providing a drug library , determining the results of administration, and identifying drug combinations that provide the desired result. In paragraph 48 a number of drugs may be tested in different combinations. In paragraph 52 profiling the combinations is discussed.

Afeyan (2005/0283320) entitled "Method and System for Profiling Biological Systems" teaches in paragraph 8 profiling a biological system for pharmacological agent response. In paragraph 11 multivariate analysis on a plurality of data sets is shown.

Khwaja (6,379,714) entitled "Pharmaceutical Grade Botanical Drugs" teaches in column 3 last paragraph, a plant extract may contain a plurality of active ingredients which exhibit a given biological activity. An aliquot is removed, separate the aliquot into a plurality of marker fractions each of which include an ingredient and the degree of biological activity for each of the marker fractions is determined. In column 4 first paragraph the invention is useful for determining if a particular botanical material meets

levels of pharmacological activity. In column 7 last paragraph, biological assay include cell proliferation assays.

Pugh (J Agricultural Food Chem) entitled "Characterization of Aloeride, A New High MW Polysaccharide from Aloe vera With Potent Immunostimulatory Activity" teaches on page 1031 isolated fractions of aloe were tested in a macrophage assay. On page 1033 Fig. 3 shows a dose response for a fraction.

The claims may differ from the above references in that they specify multivariate analysis specifically and various to separate the components of the product and various types of biological profiles.

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ multivariate analysis in the methods of analysis shown by each of the above references because each reference teaches analyzing data from more than one measurement. Employing known methods to separate chemical mixtures with the expected results would have been obvious. And the claimed biological profiles are conventional in this art. The nature of pharmacognosy is such that most all drugs originated in natural products which are mostly a mixture of chemicals and the desired activity was found in some fashion to be associated with a specific and single chemical which was then isolated or synthesized. The present claims read on this old method.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19, 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A reading of the specification reveals the point of novelty may reside in employing multivariate analysis in an interactive fashion to improve a natural product mixture by examining a biomarker. The specification reveals no natural products, no improvements and no multivariate analysis. And what biomarker may be intended is unclear.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19, 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

The claims must be carefully rewritten in accordance with standard US patent practice. There are many instances of lack of antecedent basis and improper format in the claims, many of the cited terms are not understood in context, such as “impact”,

"living systems", and others, and some of the claims simply cannot be understood in context such as claims 14-16, 19.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The abstract of the disclosure is objected to because it is in improper format and not directed to the elected invention. Correction is required. See MPEP § 608.01(b).

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are:

The format of the specification does not meet US requirements. There is no Brief Description of the Drawings for example. There are numerous misused words in the specification, for example on page 8 line 16 "polemic". On page 14 line 27 incorporation of essential material to a foreign application is improper.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Nicholson (Xenobiotica) teaches metabonomics.

Eldridge (2003/0044846) entitled "Screening of Chemical Compounds Purified from Biological Sources" teaches in the abstract, screening libraries of compounds. In paragraph 46 treating diseases is discussed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

Ralph Gitomer
Primary Examiner
Art Unit 1657